6. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

JUL 13 2012

APPLICANT:	Pinnacle Spine Group, LLC
DATE PREPARED:	June 12, 2012
CONTACT PERSON:	Rebecca K Pine 1601 Elm Street, Suite 300 Dallas, TX 75201 Phone: 760.809.5178 Fax: 760.290.3216
TRADE NAME:	InFill™ Intervertebral Body Fusion Device
COMMON NAME:	Spinal Implant
CLASSIFICATION NAME:	Intervertebral Body Fusion Device
DEVICE CLASSIFICATION:	Class 2, per 21 CFR 888.3080
PRODUCT CODE	MAX

PREDICATE DEVICES: InFill™ Intervertebral Body Fusion Device (K103729)

Substantially Equivalent To:
The modified InFill™ Intervertebral Body Fusion Device is substantially equivalent in intended use, principal of operation and technological characteristics to the InFill™ Intervertebral Body Fusion Device cleared under premarket notification K103729.

Description of the Device Subject to Premarket Notification:
The InFill™ intervertebral body fusion device is a radiolucent implantable device manufactured from PEEK and tantalum (marker material). The implant is available in various sizes to suit the individual pathology and anatomical conditions of the patient.

The InFill™ intervertebral body fusion device is provided sterile, for single use only.

Indication for Use:
InFill™ is indicated for intervertebral body fusion of the spine in skeletally mature patients. InFill™ is designed for use with autogenous bone graft to facilitate fusion. InFill™ is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar devices are to be used in patients who have had at least six months of non-operative

treatment. InFill™ is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

Technical Characteristics:
The modified InFill™ intervertebral body fusion device has identical physical and technical characteristics to the predicate device.

Performance Data:
All necessary testing has been performed for the InFill™ intervertebral body fusion device to assure substantial equivalence to the predicate device and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices.

The modified InFill™ intervertebral body fusion device met all specified criteria and did not raise new safety or performance questions.

Basis for Determination of Substantial Equivalence:
The Indication/Intended Use and the fundamental scientific technology of the modified device have not been changed and are the same as those described in the unmodified predicate device. The modified InFill™ intervertebral body fusion device is determined by Pinnacle Spine Group LLC, to be substantially equivalent to the InFill™ intervertebral body fusion device (K103729).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pinnacle Spine Group
% Ms. Rebecca K. Pine
1601 Elm Street, Suite 300
Dallas, Texas 75201

JUL 13 2012

Re: K121733
Trade/Device Name: InFill™ Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: June 12, 2012
Received: June 13, 2012

Dear Ms. Pine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. **Indications for Use Statement**

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121733

Device Name: **InFill™ Intervertebral Body Fusion Device**

Indications for Use:

InFill™ is indicated for intervertebral body fusion of the spine in skeletally mature patients. InFill™ is designed for use with autogenous bone graft to facilitate fusion. InFill™ is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar devices are to be used in patients who have had at least six months of non-operative treatment. InFill™ is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the lumbar spine.

AND/OR

Prescription Use X
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use_____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121733